K120711

510(k) Summary of Safety and Effectiveness

May 1, 2012

1. Submitter

NOV 19 2012

K-jump Health Co., Ltd.

No. 56, Wu Kung 5th Rd.
New Taipei Industrial Park
New Taipei City 24890, Taiwan

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2. Name of Device

Common/Usual Name: Non-contact Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL

3. Predicate Device

Device Name	510(k) Number	Decision Date
K-jump Health Co., Ltd. Non-Contact Infrared Thermometer, Model KI-8280	K102947	2/25/2011

4. Device Description

The Non-contact Thermometer is a compact, small and light-weight device, which is powered by a battery and can be connected to a smartphone through headphone jack, for detecting body temperature without contact to human body. The measured temperature will be displayed on the screen of a smartphone.

5. Indications for Use

The Non-contact Thermometer is intended to measure the human body temperature for children and adults without contact to human body. It can be used by consumers in household environment and doctor in clinics as reference.

6. Technological Characteristics

The Non-contact Thermometer uses an infrared sensor to detect the infrared energy radiated from objects. As the intensity of the radiated energy will depend on the temperature of the air, solid, liquid or human body, the detected infrared energy can be acquired and calculated to temperature reading. The technological characteristics of Non-contact Thermometer have no difference with predicate device.

7. Comparison to Predicate Device

The Non-contact Thermometer is substantially equivalent to the predicate devices, K102947, the Non-contact infrared Thermometer. The comparison of their technological characteristics is summarized in the table below.

Characteristics	***Non-contact Thermometer***	***Non-contact Infrared Thermometer***
510(k) Number	*K120711*	*K102947*
Intended Use	*Similar*	*Similar*
Technology		
Measurement method	*Infrared radiation detection*	*Infrared radiation detection*
Function		
Measuring Range	*Forehead Mode* *32.2℃~43.3℃, (90.0℉~109.9℉)*	*Forehead Mode* *32.2℃~43.3℃, (90.0℉~109.9℉)*
C/F Switchable	*Yes*	*Yes*
Performance		
Display Resolution	*0.1℃ (0.1℉)*	*0.1℃ (0.1℉)*
Measuring accuracy	*Forehead Mode, ±0.2℃(0.4℉)*	*Forehead Mode, ±0.2℃(0.4℉)*
Low battery detection	*Yes*	*Yes*
Environmental		
Operating condition	*10℃ ~40℃ (50.0 ~ 104℉)* *15%-95% RH*	*10℃ ~40℃ (50.0 ~ 104℉)* *15%-95% RH*
Storage condition	*-20℃ ~55℃ (-13.0 ~ 131℉)* *15%-95% RH*	*-20℃ ~55℃ (-13.0 ~ 131℉)* *15%-95% RH*
Power	*One CR2032*	*Two AAA batteries*
Physical		
Dimensions	*59 x 22 x 61 mm*	*138 x 90 x 45 mm*
Weight	*25g (with battery)*	*125g (with batteries)*

8. Performance Summary

The performance of the Non-contact Thermometer is verified and validated to comply with following recognized standards.

1. ANSI/AAMI ES60601-1:2005 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

   The Non-contact Thermometer complies with to applicable ANSI/AAMI ES60601-1 requirements including general requirements, protection against electrical hazards, protection against mechanical hazards, protection against excessive temperatures, hazardous situations and fault conditions, and constructions.

2. ANSI/AAMI/IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General Requirements for Safety; Electromagnetic Compatibility

   The Non-contact Thermometer complies with applicable ANSI/AAMI/IEC 60601-1-2 requirements including radiated emission test, electrostatic discharge immunity test, radiated RF electromagnetic field immunity test, and power frequency magnetic field immunity test.

3: ASTM E1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

   The Non-contact Thermometer complies applicable ASTM E1965-98 requirements including displayed temperature range, maximum permissible laboratory error, ambient conditions, low power supply operation, display and human interface, constructions.

9. Conclusions

The Non-contact Thermometer has the similar intended use, same fundamental scientific technology, similar technological characteristics with the predicate device. Moreover, both devices comply with similar safety and performance standards. All information described above can demonstrate the Non-contact Thermometer is substantial equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-002

November 19, 2012

Mr. JM Lin
Regulatory Affairs Representative
K-Jump Health Company, Limited
Number 56, Wu Kung 5th Road
New Taipei Industrial Park
New Taipei City, Taiwan 24890

Re: K120711
Trade/Device Name: Non-Contact Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 30, 2012
Received: October 31, 2012

Dear Mr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K-jump®

Indications for Use

510(k) Number (if known): K120711

Device Name: Non-contact Thermometer

Indications For Use:

The Non-contact Thermometer is intended to measure the human body temperature for children and adults without contact to human body. It can be used by consumers in household environment and doctor in clinics as reference.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kwame O. Ulmer

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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K-jump®

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Concurrence of CDRH, Office of Device Evaluation (ODE)

11/19/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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